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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/081,953	02/22/2002	William J. Hennen	4428.2US	6427

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EXAMINER	
CHEN, STACY BROWN	
ART UNIT	**PAPER NUMBER**
1648	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/16/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/081,953	HENNEN ET AL.	
	Examiner	Art Unit	
	Stacy B. Chen	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 December 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16 and 18-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16 and 18-23* is/are rejected.

7)☒ Claim(s) *24 and 25* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *22 February 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment filed December 14, 2006 is acknowledged and entered. Claims 1-16 and 18-22 are pending and under examination.

Response to Amendment

2. The rejection of claim 16 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention, is withdrawn in view of Applicant's amendment.

Claims Summary in view of Applicant's Amendment

3. The amendment to the claims broadens the scope to encompass a method for causing a treated animal to elicit a T-cell mediated immune response, comprising adminstering to the treated animal a quantity of a composition including an extract of an egg obtained from a source animal. Previously, the claims specified the egg as non-avian. However, only newly introduced claim 23 is drawn to a method wherein the egg extract comprises an extract of a non-avian egg. All other claims do not make this distinction, but encompass either any source animal, or an avian source animal. In view of this broadening of the scope of the claims, several rejections of record are reinstated, as outlined below.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-3, 7-16 and 18-22 under 35 U.S.C. 102(b) as anticipated by Tokoro (US 5,080,895) is reinstated. The rejection is of record and can be found in the Office action mailed March 10, 2005.

6. Claims 1-3, 7-13, 15 and 18-23 are rejected under 35 U.S.C. 102(b) as anticipated by Lee (US Patent 5,367,054). The claims are drawn to a method for causing a treated animal to elicit a T-cell mediated immune response, comprising administering a quantity of a composition including an extract of a non-avian egg obtained from a non-avian source animal, said extract comprising transfer factor, generated by said source animal in a T-cell mediated immune response to at least one antigenic agent, in a concentration greater than that present in the egg and in a sufficient quantity to initiate said T-cell mediated immune response in the treated animal.

Lee discloses a method for isolating and purifying immunoglobulins or fragments thereof or other biologically active factors from non-immune or immune egg yolk extracts (abstract). Lee's immune eggs are collected from any egg-producing member of the avian, reptile, amphibian or fish family which have been immunized (col. 4, lines 58-63). The antigens that can be used to immunize the egg-producing subject include bacteria and other desired antigens for immunization (col. 8, lines 16-31). Although Lee does not mention the presence of transfer factor, one would expect transfer factor to be present in Lee's eggs because the subjects are exposed to antigens that are capable of inducing a T-cell mediated immune response. Further, amphibians, reptiles and fish are exposed to a plurality of natural antigens that are present in the

environment regardless of human-controlled exposure to antigens via vaccination. Lee teaches that the products purified from the eggs are for pharmaceutical purposes such as passive immunization or as a health food ingredient (col. 1, lines 29-33).

Although Lee does not mention transfer factor or its molecular weight, the presence of transfer factor in Lee's composition is expected because Lee immunized hens with antigens that induce a T-cell response, and collects the immunoglobulin from the immune eggs. The process of IgY purification concentrates the amount of transfer factor expected to be present in the immunoglobulin fraction of the immune eggs. In column 5, line 38 through col. 6, line 14, Lee describes the process of extraction and phase separation of IgY. Through the process described, IgY as well as transfer factor is expected to be present in the final product described by Lee. During ultrafiltration, the composition is filtered with a 30K molecular weight cut off. The resulting retentate is dried or further purified (col. 6, lines 1-5). Therefore, the claims are anticipated by Lee's disclosure.

Reinstated Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. The rejection of claims 4-6 under 35 U.S.C. 103(a) as obvious over Tokoro in view of Kirkpatrick (US 5,840,700) is reinstated in view of Applicant's amendment to the claims. The rejection is of record and can be found in the Office action mailed March 10, 2005.

9. Claims 4-6 and 14 are rejected under 35 U.S.C. 103(a) as obvious over Lee, as applied to claim 1, in view of Kirkpatrick (US 5,840,700). The claims are drawn to a method of eliciting a T-cell mediated immune response in an animal by administering an extract of a non-avian egg including transfer factor formulated for application to the skin of an animal, nasal administration and parenteral administration. Specifically, the transfer factor molecules are specific for Newcastle disease virus, rubeola virus, mumps virus, rubella virus, Epstein-Barr virus, hepatitis B or H. pylori. More specifically, the egg extract is purified away from proteins or peptides having molecular weights of greater than about 8,000 daltons.

The rejection above establishes the Office's position that transfer factor was inherently present in Lee's product. Lee is silent on the routes of administration instantly claimed, however, one would have been motivated to use them with the product of Lee because Kirkpatrick teaches that transfer factor can be administered intravenously, intramuscularly, subcutaneously or orally. Although Lee does not explicitly say that transfer factor is present in their product, one would have been motivated to formulate their product for different applications. One would have been motivated to administer the transfer factor via other routes depending on the subject receiving it. One would have had a reasonable expectation of success that the product of Lee would have been formulated successfully for other routes of administration because Kirkpatrick formulates transfer factor in various mediums.

Further, although Lee does not specifically mention the antigens instantly claimed, Kirkpatrick discloses the production of transfer factor specific for viruses, such as Epstein-Barr virus (col. 7, lines 60-67). One would have been motivated to use antigens from Epstein-Barr in Lee's method because Lee teaches that the antigens that can be used to immunize the egg-

producing subject include bacteria and other desired antigens for immunization (col. 8, lines 16-31). One would have had a reasonable expectation of success that immunizing Lee's eggs with Epstein-Barr virus would have produced transfer factor specific for Epstein-Barr virus because Kirkpatrick produces transfer factor specific for Epstein-Barr virus with hens eggs. Therefore, the invention would have been obvious to one of ordinary skill in the art at the time the invention was made.

10. Applicant's arguments have been carefully considered but fail to persuade. Applicant's arguments are primarily directed to the following:

- Applicant notes that Lee describes methods for purifying IgY from eggs, of 90% or greater purity. Applicant notes that in Lee's method, phase separation includes separation of an aqueous phase, from which IgY is purified, from a lipid phase (precipitate phase). Applicant argues that each of the purification paths in Figure 1 include at least one process that would result in the removal of transfer factor and, presumably, the transfer factor-like component taught in Tokoro. Such steps include ultrafiltration, gel filtration and desalting. Applicant argues that when the final product is administered to mammals, it no longer contains transfer factor.
  - In response, the Office acknowledges that the purification pathways described in Lee's Figure 1 would most likely remove transfer factor from the purified IgY composition. However, Lee does not limit the purification of IgY to the processes in Figure 1. For example, claim 1 of the Lee patent is drawn to a method for purifying IgY from an immune egg by diluting and homogenizing the yolk,

extracting the homogenate and recovering the aqueous phase. The aqueous phase not only contains IgY, but would also contain transfer factor. Although Lee does not say that transfer factor is present in the aqueous phase, one would expect transfer factor to be present given the circumstances of which the egg yolks were processed. Even Applicant notes that transfer factor would initially be present in the aqueous phase. Therefore, Applicant's argument is based on further purification steps which are not required according to claim 1 of the Lee patent. While it may be preferable to further process the aqueous phase, Lee indicates that the aqueous phase is a purified product and that purified products can be administered (col. 3, lines 38-40 and col. 4, lines 13-19). Lee discloses that the two major products of the invention are the IgY protein obtained as a retentate from ultrafiltration of the aqueous phase and the pure IgY obtained from further processing. Regardless these two major products, Lee also considers the aqueous phase itself to be a purified product that can be further purified (col. 3, lines 52-57).

- Applicant argues that the teachings of Lee and Kirkpatrick do not support a *prima facie* case of obviousness because their teachings are mutually exclusive. Lee's teachings are limited to methods for purifying antibodies, while Kirkpatrick's method is drawn to purifying transfer factor from other molecules, including antibodies.
  - The Office acknowledges that the teachings of Lee and Kirkpatrick do not both teach purification of transfer factor. However, the purpose for which Kirkpatrick is brought in as a secondary reference, is to show that one would have been

motivated to use antigens from Epstein-Barr (as taught in Kirkpatrick for generating immune factors) in Lee's method because Lee teaches that the antigens that can be used to immunize the egg-producing subject include bacteria and other desired antigens for immunization (col. 8, lines 16-31). The test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art.

- Further, in response to Applicant's argument that the Office's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. Therefore, the rejection is maintained for reasons of record.

Conclusion

11. No claim is allowed. The subject matter of claims 24 and 25 is free of the prior art of record. Claims 24 and 25 are objected to for depending from rejected claims 1 and 20.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stacy B. Chen whose telephone number is 571-272-0896. The examiner can normally be reached on M-F (7:00-4:30). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Stacy B. Chen 3/15/07

STACY B. CHEN
PRIMARY EXAMINER